IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: David J. Ecker, et al.

Serial No.: 10/660,997 Group Art Unit: Not Yet Assigned

Filing Date: September 12, 2003 Examiner: Not Yet Assigned

For: METHODS FOR RAPID DETECTION AND IDENTIFICATION OF BIOAGENTS IN EPIDEMIOLOGICAL AND FORENSIC INVESTIGATIONS

DATE OF DEPOSIT: 23 December 2003
I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450

TYPED NAME:Paul K. Legaard
REGISTRATION NO: 38,534

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

This Information Disclosure Statement is being filed:

☐ within three months of the filing date of the patent application.

☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.

☒ **before** the mailing date of a first Office Action on the merits.

☐ **after** the mailing date of a first Office Action on the merits, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:

☐ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);

or

☐ the Fee of $180.00 set forth in 37 C.F.R. § 1.17(p); or

☒ No fee is owed by the applicant(s).

☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of $180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.

☐ **after** the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before, or simultaneously with, the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), a Petition requesting consideration of the Information Disclosure Statement and the Petition Fee of $130.00 set forth in 37 C.F.R. § 1.17(i)(1) (see "Statement," "Petition," and "Fees" below).

☒ Copies of references (S1-S44) listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are enclosed herewith

EXCEPT THAT:

☐ In view of the voluminous nature of references @@, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ In accordance with 37 C.F.R. § 1.98(d), copies of the following references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.

☐ Copies of references listed on the attached PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449 were previously cited by or submitted to the U.S. Patent and Trademark Office in parent application Serial No. _____ filed on _____.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Statement under 37 C.F.R. § 1.97(e)

☐ The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

Petition

☐ Applicant(s) hereby petitions the Assistant Commissioner to consider the references listed in this Information Disclosure Statement, on the enclosed PTO Form SB/08A and PTO Form SB/08B, formerly known as PTO Form 1449, and the examination of the above-identified patent application.

Fees

☒ No Fee is owed by the applicant(s).

☐ The Information Disclosure Statement Fee of $180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.

☐ The Petition Fee of $130.00 under 37 C.F.R. § 1.17(i)(1) is enclosed herewith.

Method of Payment of Fees

☐ Attached is a check in the amount of $_____. This form is submitted in duplicate.

☐ Charge Deposit Account No. 50-1275 in the amount of $_____. This form is submitted in duplicate.

☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.

☒ No fee or Statement is required under 37 C.F.R. § 1.97(b).

Respectfully submitted,

Dated: 23 DECEMBER 2003

Paul K. Legaard
Registration No. 38,534

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PTO/SB/21 (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/660,997
Filing Date	September 12, 2003
First Named Inventor	David J. Ecker
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission: 10	Attorney Docket Number: IBIS0063-100/DIBIS-0002US.P2

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s)
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below)*:
  References S1-S44

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Paul K. Legaard/Reg. No. 38,534
Signature	Paul K Legaard
Date	23 DECEMBER 2003

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name	Paul K. Legaard		
Signature	Paul K Legaard	Date	23 DECEMBER 2003

PTO/SB/08b(05-03)
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 5

Complete if Known	
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First Named Inventor	David J. Ecker
Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	IBIS0063-100/DIBIS-0002US.P2

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	S1	BAKER, et al., "Review and re-analysis of domain-specific 16S primers," J. Microbiol. Methods (2003) 55:541-555.	
	S2	BENSON, et al., "Advantages of Thermococcus kodakaraenis (KOD) DNA polymerase for PCR-mass spectrometry based analyses," J. Am. Soc. Mass Spectrom. (2003) 14:601-604.	
	S3	BLACK. et al., "Detection of trace levels of tricothecene mycotoxins in human urineby gas chromatography-mass spectrometry," J. Chromatog. (1986) 367:103-115.	
	S4	CAMPBELL and HUANG, "Detection of California serogroup Bunyavirus in tissue culture and mosquito pools by PCR," J. Virol. Methods (1996) 57:175-179.	
	S5	CHEN, et al., "A universal PCR primer to detect members of the Potyviridae and its use to examine the taxonomic status of several members of the family," Arch. Virol. (2001) 146:757-766.	
	S6	CONRADS, et al., "16S-23S rDNA internal transcribed spacer sequences for analysis of the phylogenetic relationships among species of the genus Fusobacterium," Intl. J. System. Evol. Micrbiol. (2002) 52:493-499.	
	S7	DASEN, et al., "Classification and identification of Propioibacteria based on ribosomal RNA genes and PCR," System. Appl. Microbiol. (1998) 21:251-259.	
	S8	DEFORCE, et al., "Characterization of DNA oligonucleotides by coupling of capillary zone electrophoresis to electrospray ionization Q-TOF mass spectrometry," Anal. Chem. (1998) 70:3060-3068.	
	S9	DEMESURE, et al., "A set of universal primers for amplification of polymorphic non-coding regions of mitochondrial and chloroplast DNA in plants," Mol. Ecol. (1995) 4:129-131.	
	S10	FLORA. et al., "Dual-micro-ESI source for precise mass determination on a quadrupole time-of-flight mass spectrometer for genomic and proteomic applications," Anal. Bioanal. Chem. (2002) 373:538-546.	
	S11	FOX, et al., "Identification of Brucella by ribosomal-spacer-region PCR and differentiation of Brucell canis from other Brucella spp. pathogenic for humans by carbohydrate profiles," J. Clin. Microbiol. (1998) 36:3217-3222.	

Examiner Signature		Date Considered	

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This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 5

Complete if Known	
Application Number	10/660,997
Filing Date	September 12, 2003
First Named Inventor	David J. Ecker
Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	IBIS0063-100/DIBIS-0002US.P2

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	S12	FOX et al., "Report of the 'Bioterrorism Workshop'", J. Microbol. Methods (2002) 51:247-254.	
	S13	GRIFFEY and GREIG, "Detection of base pair mismatches in duplex DNA and RNA oligonucleotides using electrospray mass spectrometry," SPIE (1997) 2985:82-86.	
	S14	GRIFFIN, et al., "Direct genetic analysis by matrix-assisted laseer desorption/ionization mass spectrometry," proc. Natl. Acad. Sci. USA (1999) 96:6301-6306.	
	S15	HANNIS and MUDDIMAN, "Accurate characterization fo the tyrosine hydroxylase forensic allele 9.3 through development of electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry," Rapid. Comm. Mass Spectrom. (1999) 13:954-962.	
	S16	HANNIS and MUDDIMAN, "Genotyping short tandem repeats using flow injection and electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry," Rapid. Comm. Mass Spectrom. (2001) 15:348-350.	
	S17	HANNIS and MUDDIMAN, "Detection of double-stranded PCR amplicons at the attomole level electrosprayed from low nanomolar solutions using FT-ICR mass spectrometry," Fresenius J. Anal Chem. (2001) 369:246-251.	
	S18	HAYASHI, et al., "Phylogenetic analysis of the human gut microbiota using 16S rDNA clone libraries and strictly anaerobic culture based methods," Microbiol. Immunol. (2002) 46:535-548.	
	S19	HOFFMANN, et al., "Universal primer set for the full-length amplification of all influenza A viruses," Arch. Virol. (2001) 146:2275-2289.	
	S20	ISOLA, et al., "MALDI-TOF mass spectrometric method for detection of hybridized DNA oligomers," Anal. Chem. (2001) 73:2126-2131.	
	S21	JANKOWSKI and SOLER, "Mass spectrometry of DNA: Part 2* Quantitative estimation of base composition," Eur. J. Mass Spectrom. Biochem. Med. Environ. Res. (1980) 1:45-52.	
	S22	KAGEYAMA and BENNO, "Rapid detection f human fecal Eubacterium species and related genera by tested PCR method," Microbiol. Immunol. (2001) 45:315-318.	

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Sheet 3 of 5

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	S23	LITTLE, et al., "Rapid sequencing of oligonucleotides by high-resolution mass spectrometry," J. Am. Chem. Soc. (1994) 116:4893-4897.	
	S24	LIU, et al., "Improving the microdialysis procedure for electrospray ionization mass spectrometry of biological samples," J. Mass Spectrom. (1997) 32:425-431.	
	S25	MANGRUM, et al., "Solution composition and thermal denaturation for the production of single-stranded PCR amplicons: piperidine-induced destabilization of the DNA duplex," J. Am. Soc. Mass Spectrom. (2002) 13:232-240.	
	S26	McCABE, et al., "Bacterial species identification after DNA amplification with a universal primer pair," Mol. Genet. Metab. (1999) 66:205-211.	
	S27	MEIYU, et al., "Detection of flaviviruses by reverse transcriptase-polymerase chain reaction with the universal primer set," Microbiol. Immunol. (1997) 41:209-213.	
	S28	MORICCA, et al., "Detection of Fusarium oxysporum f.sp. vasinfectum in cotton tissue by polymerase chain reaction," Plant Pathol. (1998) 47:486-494.	
	S29	MUDDIMAN, et al., "Characterization of PCR products from Bacilli using electrospray ionization FTICR mass spectrometry," Anal Chem. (1996) 68:3705-3712.	
	S30	NAGPAL, et al., "Utility of 16S-23S rRNA spacer region methodology: how similar are interspace regions within a genome and between strains for closely related organisms?," J. Microbiol. Methods (1998) 33:211-219.	
	S31	NULL, et al., "Preparation of single-stranded PCR products for electrospray ionization mass spectrometry using the DNA repair enzyme lambda exonuclease," Analyst (2000) 125:619-626.	
	S32	NULL, et al., "Evaluation of sample preparation techniques for mass measurements of PCR products using ESI-FT-ICR mass spectrometry," Am Soc. Mass Spectrom. (2002) 13:338-344.	

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Sheet 4 of 5

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Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
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	S33	NULL and MUDDIMAN, "Determination of a correction to improve mass measurement accuracy of isotopically unresolved polymerase chain reaction amplicons by electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry," Rapid Comm. Mass Spectrom. (2003) 17:1714-1722.	
	S34	NULL and MUDDIMAN, "Perspectives on the use of electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry for short tandem repeat genotyping in the post genome era," J. Mass Spectrom. (2001) 36:589-606.	
	S35	NULL, et al., "Genotyping of simple and compound short tandem repeat loci using electrospray ionization Fourier transform ion cyclotron resonance mass spectrometry," Anal. Chem. (2001) 73:4514-4521.	
	S36	NULL, et al., "Implications of hydrophobicity and free energy of solvation for characterization of nucleic acids by electrospray ionization mass spectrometry," Anal. Chem. (2003) 75:1331-1339.	
	S37	PENG, et al., "Rapid detection of Shigella species in environmental sewage by an immunocapture PCR with universal primers," App. Environ. Microbiol. (2002) 68:2580-2583.	
	S38	POMERANTZ, et al., "Determination of oligonucleotide composition from mass spectrometrically measured molecular weight," J. Am. Soc. Mass Spectrom. (1993) 4:204-209.	
	S39	ROSS, et al., "Discrimination of single-nucleotide polymorphisms in human DNA using peptide nucleic acid probes detected by MALDI-TOF mass spectrometry," Anal. Chem. (1997) 69:4197-4202.	
	S40	SCARAMOZZINO, et al., "Comparison of Flavivirus universal primer pairs and development of a rapid, highly sensitive heminested reverse transcription-PCR assay for detection of flaviviruses targeted to a conserved region of the NS5 gene sequences," J. Clin. Microbiol. (2001) 39:1922-1927.	
	S41	SHAVER, et al., "Restriction fragment length polymorphism of rRNA operons for discrimination and intergenic spacer sequences for cataloging of Bacilus subtilis sub-groups," J. Microbiol. Methods (2002) 50:215-223.	
	S42	SRINIVASAN, et al., "Matrix-assisted laser desorption/ionization time-of-flight mass spectrometry as a rapid screening method to detect mutations causing Tay-Sachs disease," Rapid Comm. Mass Spectrom. (1997) 11:1144-1150.	
	S43	STEFFENS and ROY, "Sequence analysis of mitochondrial DNA hypervariable regions using infrared fluorescence detection," Bio/Techniques (1998) 24:1044-1046.	

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Sheet 5 of 5

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First Named Inventor	David J. Ecker
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Examiner Name	Not Yet Assigned
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	S44	WUNSCHEL, et al., "Mass spectrometric characterization of DNA for molecular biological applications: advances using MALDI and ESI," Adv. Mass Spectrom., Vol. 14, Karjalainen, et al., (eds.) 1998, Elsevier, Amsterdam.	

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